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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/554,333 | 08/07/2000 | Mark Parrington | 1038-1030 MI | 1862 |
| 7590 02/22/2005 | | | EXAMINER | |
| Sim & McBurney 330 University Avenue 6th Floor ONTARIO, M5G 1R7 CANADA | | | VOGEL, NANCY S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/554,333 | Applicant(s) PARRINGTON ET AL. | |
| | Examiner Nancy T. Vogel | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/3/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6 and 8-14 are pending in the case.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1-5, 8, 9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dubensky et al. (WO 96/17072) (previously cited).

This rejection is maintained for the reasons made of record in the previous Office action, mailed 6/3/04.

Applicant has argued in their response filed 12/3/04, that Dubensky et al. does not anticipate the claims due to applicant's amendment to claims 1 and 9, in which language reciting that "the claimed vectors comprise a heterologous splice site sequence at a location which generates perfect splice junctions and restores the function of the alphavirus when removed" (page 9 of the arguments). However, it is maintained that the reference does disclose vectors comprising at least one splice site, i.e. an intron containing splice sites, and that since the reference discloses that the inserted intron is removed by splicing from the pre-RNA, said removal would inherently restore any "function" of the alphavirus. Therefore, applicant's arguments are not found convincing.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubensky et al. (WO 96/17072) in view of Li et al. (WO 96/40945) (both previously cited).

This rejection is maintained for the reasons made of record in the previous Office action, mailed 6/3/04.

Applicant has again argued in their response filed 12/3/04, that Dubensky et al. does not anticipate the claims due to applicant's amendment to claims 1 and 9, in which language reciting that "the claimed vectors comprise a heterologous splice site sequence at a location which generates perfect splice junctions and restores the function of the alphavirus when removed" (page 9 of the arguments). However, it is maintained that the reference does disclose vectors comprising at least one splice site, i.e. an intron containing splice sites, and that since the reference discloses that the inserted intron is removed by splicing from the pre-RNA, said removal would inherently restore any "function" of the alphavirus. Applicant additionally state that Li et al. does not teach this element of the claims as amended. However, since it is maintained that Dubensky et al. does teach this element for the reasons set forth above, Li et al. need not teach this element. Therefore, applicant's arguments are not found convincing.

Double Patenting

Claims 4-6 and 8-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,475,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons made of record in the previous Office action, mailed 6/3/04.

In response to this rejection, applicants have requested that the rejection be held in abeyance until allowable subject matter has been agreed upon. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TERRY MCKELVEY
PRIMARY EXAMINER